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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,829	09/09/2003	Nikolai M. Krivitski	86017.000037	1750
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Stephen B. Salai, Esq. Harter Secrest & Emery LLP 1600 Bausch & Lomb Place Rochester, NY 14604-2711			EXAMINER PANI, JOHN	
			ART UNIT 3736	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/657,829

Applicant(s)

KRIVITSKI ET AL.

Examiner

JOHN PANI

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2009 and 17 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/2009 has been entered.

Drawings

2. The drawings were received on 3/17/2009. These drawings are not acceptable. The drawings are objected to because Figures 17 and 18 appear to contradict paragraphs [00142-00143] which describe them. Examiner notes that the title of the section containing these paragraphs is "Thermodilution catheter placed with the blood flow" [emphasis added], and that paragraph [00142] states "part of the introduced injectate volume will exit the catheter 10 downstream of the thermal sensor" [emphasis added], and that "'a' is the portion of the indicator that passes from the catheter through the distal aperture in the guide wire lumen". These statements have led the Examiner to believe that the blood flow indicated in Figs. 17 and 18 by arrows found at the right of the drawing are pointing in a direction contrary to what was intended. As currently depicted, only the injectate exiting the distal aperture would contact the thermal sensor

36, and it does not appear that this configuration would produce an accurate blood flow measurement using equations 26 or 27, because the guidewire is detailed as substantially blocking this aperture, and therefore the equations would essentially be using the volume of injectate exiting ports 34 which would not even contact sensor 36. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The amendment to the specification filed 2/3/2009 has been received. The disclosure is objected to because of the following informalities: In line 2 it is suggested

to insert --port-- after "such as a guide wire" in order to conform with paragraph [00038] which appears to provide support for amendment to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 19 recites "wherein compensating for passage of the indicator through terminal port includes compensating...." This limitation implies that "compensating" has been previously detailed in the claims. However, the term "compensating" has been deleted from claim 14, therefore the above cited limitation lacks antecedent basis in the claims.

7. Claim 20 recites "wherein measuring the blood flow rate corresponds to a relationship...." It is unclear in what way "measuring...corresponds to the relationship...." limits the claim. Particularly, it is unclear whether the cited limitation requires that the method includes a step of calculating the blood flow rate using the claimed equation or merely requires the measuring configuration be described by (i.e. correspond to) the equation of the relationship. For purposes of rejections over prior art, the latter interpretation has been applied herein. Furthermore, line 5 recites "where

Q is a blood flow rate". It is unclear whether this blood flow rate is the same or different from "a blood flow rate" of line 1 of claim 14, the lack of clarity rendering the claim indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 14, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,089,103 to Smith ("Smith").

10. Smith teaches:

In reference to Claim 14

A method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port ("distal opening") of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); and measuring the blood flow rate based on the passage of the indicator through the terminal port (col. 4 lines 20-40).

In reference to Claim 17

The method of claim 14 (see above) further comprising passing the indicator through the indicator lumen to contact a portion of the guide wire (col. 4 lines 34-37).

In reference to Claim 19

The method of claim 14 (see above) wherein compensating for passage of the indicator through terminal port includes compensating for a volume of the indicator passing through the terminal port (for example, by noting when the volume is displaced using the pressure signal).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 14 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 3,726,269 to Webster, Jr. ("Webster").

In reference to Claim 14

Webster teaches a method of measuring a blood flow rate, the method comprising: passing a guide wire (26) through an indicator lumen (16) in an elongate catheter body (12) to pass a portion of the guide wire through a terminal port (64, etc.) of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through an injection port (27) intermediate the terminal port and a proximal end of the catheter body (col. 5); and measuring the blood flow rate

based on the passage of the indicator through the injection port (col. 8-9). Webster does not explicitly teach that indicator passes through the terminal port, or that the blood flow rate is measured based on the passage of the indicator through the port. Webster does teach that the anterior end is "effectively closed". Because Webster does not explicitly teach that the end is in fact closed, it is submitted that in repeatedly applying the method it would have been likely that, at least occasionally, a very small amount of the injected fluid to have escaped from the distal opening due to the pressure applied to it. Because this leaked fluid would occur upstream of the temperature sensors, the fluid would pass the sensors and the measuring would at least be partly based on the passage of the indicator through the terminal port. Thus, claim 14 is obvious in view of Webster.

In reference to Claim 16

Webster teaches the method of claim 14 (see above), and further teaches passing the guide wire through a reduced cross sectional area of the indicator lumen (see Figs. 6 and 8).

In reference to Claim 17

Webster teaches the method of claim 14 (see above) and teaches passing the indicator through the indicator lumen to contact a portion of the guide wire (inherently as the guide wire is in the lumen during injection).

In reference to Claim 18

Webster teaches the method of claim 14 (see above) further comprising passing the guide wire through a reduced cross sectional area of the indicator lumen to increase

a flow of the indicator through the injection port (by placing 26 in the terminal port, this increase would occur at least relative to a situation where the guide wire was not there).

In reference to Claim 19

Webster teaches the method of claim 14 (see above) and further teaches compensating for passage of the indicator through terminal port includes compensating for a volume of the indicator passing through the terminal port (by passing enough through 27, the small leakage through the distal tip would be compensated for).

13. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith as applied to claim 14 above, and further in view of US Pat. No. 5,221,256 to Mahurkar ("Mahurkar").

In reference to Claims 16 and 18

Smith teaches the method of claim 14 (see above) and passing the guide wire through the indicator lumen to increase a flow of the indicator through the injection port (as its presence would increase flow through these compared with a situation in which it was not there) but does not explicitly teach a reduced cross sectional area of the indicator lumen. Mahurkar teaches (see Fig. 4) a catheter with a fluid injection lumen with multiple ports (21, 22). The injection lumen tapers and has a reduced cross-sectional area at its tip. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Smith by making the catheter with a similar tip and lumen configuration so that the distal tip would be more flexible and atraumatic as implicitly taught by Mahurkar.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webster as applied to claim 14 above, and further in view of US Pat. No. 6,231,498 to Pfeiffer et al. ("Pfeiffer '498").

Webster teaches the method of claim 14 (see above), but does not explicitly teach how the blood flow rate is calculated. Pfeiffer teaches that flow rate in thermodilution corresponds to the equation detailed at the top of column 2 of Pfeiffer. It would have been obvious to one having ordinary skill at the time of the invention to have used the equation detailed by Pfeiffer in the method of Webster in order to calculate the blood flow rate, because both Pfeiffer and Webster are directed towards thermodilution methods which determine flow rates, and it is obvious to use an art recognized equation for calculating a desired value in a method that does not explicitly detail one. Because the equation of Pfeiffer is the same as the equation claimed except that Pfeiffer does not include the $(1-a)$ term, and because this term describes the amount of injectate that flows from the injection ports, this would correspond to the claimed relationship at least in situations where the leakage from the terminal port was very small. (Note, this application of the Pfeiffer '498 reference is based on the interpretation that the claim language does not currently require a step of calculating the flow using the claimed invention).

Response to Arguments

15. Applicant's arguments with respect to claims 14 and 16-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736